NACDS
National Association of Chain Drug Stores

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President & CEO

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July 3, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 10857

RE: Prescription Drug Marketing Act (PDMA) of 1987; Prescription Drug Amendments (PDA) of 1992; Reopening of Administrative Record (Dockets Nos. 92N-0297, 88N-0258)

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide additional comments on specific sections of the 1987 PDMA and the 1992 PDA, as well as the PDMA and PDA implementing regulations, relating to the conditions under which secondary wholesalers can sell prescription products.

NACDS membership consists of more than 150 retail chain community pharmacy companies operating over 32,000 community pharmacies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 94,000 pharmacists. The chain community pharmacy industry is comprised of more than 19,300 traditional chain drug stores, 7,800 supermarket pharmacies and 5,300 mass merchant pharmacies. Chain operated community retail pharmacies fill over 60 percent of 3 billion prescriptions dispensed annually in the United States. Many of our members purchase pharmaceuticals from, and sell to, secondary pharmaceutical wholesalers.

PDMA's goal is to assure that only quality pharmaceutical products are distributed in the United States. The final regulations were issued on December 3rd, 1999, and were scheduled to become effective December 4th, 2000. On May 3, 2000, however, FDA suspended two specific parts of the final regulation regarding the conditions under which these secondary wholesalers can operate. We support suspension of these particular provisions, and believe that changes need to be made to these sections – either through legislation or regulation – that will maintain the viability of the secondary wholesaler pharmaceutical marketplace.

That is because these requirements, if implemented, will cause significant disruption in this marketplace. Secondary wholesalers have traditionally served as a lower-cost wholesale source of quality pharmaceutical products for pharmacies, especially those in rural areas that may not be served by larger full-line wholesalers. The products obtained through these sources help to reduce pharmaceutical product costs for private and public payors, including Medicaid, and many consumers who pay out-of-pocket for medications, such as Medicare beneficiaries.

In particular, we believe that Sections 203.3(u) and 203.50(a) of the final PDMA regulations would place unreasonable and impractical paperwork and tracking requirements on these wholesalers before they could sell these products to community pharmacies, or before some of our pharmacy operators could sell these products back to wholesalers or other pharmacies.

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We do not believe that it was the intent of Federal policymakers in enacting PDMA to create significant burdens for the distribution of quality pharmaceutical products by secondary wholesalers, or eliminate them from the marketplace. In fact, regulations that have been in effect since 1990, already require wholesalers to maintain records of transactions for two years See 21 CFR 205.50(f)(2). This information is already available to FDA, state regulators, and law enforcement agencies. Given these existing requirements, we question the need for additional pedigree requirements, which would appear to simply add costs to the system. Moreover, it is simply impractical to expect secondary wholesalers to maintain extensive pedigrees of the sales of pharmaceutical products – all the way back to the manufacturer or authorized distributor - without requiring that such entities provide these pedigrees.

We also oppose the part of the regulation that empowers the manufacturer to solely determine those entities that are "authorized distributors" of pharmaceutical products. Current FDA guidance on PDMA implementation – in effect since 1988 – designates a wholesaler or chain pharmacy as an "authorized distributor" if a manufacturer has two transactions with the entity within a 24 month period. We support this type of approach to the designation of "authorized distributor". The final regulations, however, would only allow a manufacturer to make such a designation through a written agreement with the entity, regardless of the volume of sales or the number of transactions between the manufacturer and the entity.

This approach would create a competitive imbalance in favor of the manufacturer. Time, cost, and other constraints or considerations may preclude a manufacturer from entering into these written "authorized distributor" agreements with many of these secondary wholesalers and pharmacies. As a result, the secondary wholesalers would be unable to gain such a designation, and would thus be subject to the extensive new pedigree requirements. As already discussed, they would likely be unable to obtain these pedigrees, and would be forced out of business. The ultimate effect of these requirements would be to reduce competition in this marketplace to the detriment of consumers, as well as public and private health care programs.

We commend the agency's decision to suspend these two requirements until the original statute can be changed. We will work with Members of Congress to assure that necessary changes are made to assure the continued viability of this market. Please direct any questions about these comments to John Coster, Ph.D., R.Ph., NACDS Vice President, Federal and State Programs, at 703-549-3001 X 126. Thank you.

Sincerely,

S. Lawrence Kocot
Senior Vice President and General Counsel